

I hereby certify that this correspondence is being deposited with the U.S. Postal Service with sufficient postage as First Class Mail, in an envelope addressed to: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450, on the date shown below.

Dated: September 6, 2006 Signature: _____

Jeffrey S. Sharp

Docket No.: 27656/40760
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Ghanem E. Ghanem et al.

Application No.: 10/518,610

International Filing Date: June 23, 2003
§371 Filing Date: Dec. 23, 2004

For: DRUG TRANSPORT AND DELIVERY
SYSTEM

Confirmation No.: 3634

Art Unit: Not Yet Assigned

Examiner: Not Yet Assigned

**AMENDMENT AND RESPONSE TO NOTIFICATION OF MISSING
REQUIREMENTS UNDER 35 U.S.C. §371 IN THE UNITED STATES
DESIGNATED/ELECTED OFFICE (DO/EO/US)**

AND

**PETITION UNDER 37 C.F.R. §1.47(A) AND SUBMISSION OF DECLARATION OF
A CO-INVENTOR (GHANEM) ON BEHALF OF HIS CO-INVENTOR (MEHLEM)
WHERE MEHLEM HAS REFUSED TO EXECUTE HIS DECLARATION**

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This paper and the materials enclosed herewith are filed in response to the "Notification of Missing Requirements Under 35 U.S.C. 371 in the United States Designated/Elected Office" mailed March 29, 2006. This response is timely filed as a petition for a four-month extension of time to September 29, 2006 is submitted herewith.

Amendments to the Specification: There are no amendments to the specification in this submission.

Amendments to the Claims: There are no amendments to the claims in this submission.

An Amendment to the Sequence Listing is described on page 2 of this submission.

Remarks/Arguments begin on page 3 of this submission.

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In the Sequence Listing:

Please delete the sequence listing as originally filed (pages 1-2) and substitute therefore the corrected sequence listing (pages 1-2) filed herewith in paper and computer readable form.

REMARKS

The Notice to File Missing Requirements, mailed March 29, 2006, required submission of an Inventor's Declaration. In response, Applicants respectfully submit the Declaration and Power of Attorney of Ghanem, a Petition to accept the Declaration of Ghanem on behalf of his co-inventor Mehlem, who refuses to execute his Declaration, and Part 2 Copy of the Notice.

Applicant (Ghanem) hereby petitions for acceptance of the Declaration on behalf of his co-inventor Mehlem, who refuses to execute his Declaration. This petition under 37 C.F.R. §1.47 is submitted along with the Declaration and Power of Attorney document executed by Ghanem which was not executed by his co-inventor Mehlem because Mehlem refuses to execute the Declaration and Power of Attorney.

Submitted herewith is the statement by Dr. Mehlem's co-inventor, Professor Ghanem, in which Professor Ghanem relates the submission of the application papers including specification and claims (there are no drawings) to Dr. Mehlem, Dr. Mehlem's initial cooperation regarding execution of a Declaration that was found to be defective by the USPTO, and Dr. Mehlem's later refusal to cooperate and sign a the corrected Declaration submitted herewith.

Specifically, Professor Ghanem states that Dr. Mehlem was presented with the Application papers including specification and claims (there were no drawings) and a Declaration (Declaration 1) between late March and early May 2005 and that Dr. Mehlem signed and took steps to return the Declaration to the undersigned attorney. Declaration 1 was submitted to the USPTO by first class mail on June 14, 2005. On March 29, 2006 a further Notice of Missing Requirements under 35 U.S.C. §371 was mailed by the USPTO stating, in part, that Declaration 1 was defective for failing to identify the application by its International application number and international filing date.

Professor Ghanem was then supplied with a revised Declaration (Declaration 2) substituting the International application number and international filing date for the US Serial Number and Express mailing date. Professor Ghanem then forwarded Declaration 2 to Dr. Mehlem on June 14, 2006 with a request that he sign the declaration. Roughly two weeks later, Professor Ghanem received a letter from Dr. Mehlem dated June 28, 2006 in which Dr. Mehlem acknowledged receipt of Professor Ghanem's request that he execute Declaration 2 but stated that because of differences between the two inventors and for various stated and

unstated reasons including "the inability to bring the Delivery System to market" that he would not cooperate with Professor Ghanem or accede to his request that he execute Declaration 2.

The last known address of Dr. Mehlem is:

Dr. Francesco Mehlem
Undenhofstrasse 2
CH-3042 Worblaufen
Switzerland


For these reasons it is requested that the Declaration signed by Professor Ghanem submitted herewith be accepted and treated as having been signed by him on behalf of Dr. Mehlem.

The Notice also required the submission of a substitute Sequence listing since the copy received in the U.S. Patent and Trademark Office does not comply with the requirements of 37 CFR §1.822 and/or §1.823. In response, Applicant respectfully submits a substitute sequence listing on one diskette along with a statement indicating the content of the diskette submitted herewith is identical, does not add new matter, and requests entry of the same into the application.

Applicant submits herewith the requisite surcharge of \$130.00 as set forth in 37 C.F.R. §1.16 (f) and 37 C.F.R. §1.492(h) for late submission of an oath/declaration, a fee of \$1590.00 for the 4 month extension of time under 37 § C.F.R. 1.17(a)(4) , and the petition fee of \$200.00 under 37 § C.F.R. 1.17(g). The Director is hereby authorized to charge or credit Deposit Account No. 13-2855 under Order No. 27656/40760 for any under or overpayment of all required fees.

Dated: September 6, 2006

Respectfully submitted,

By 
Jeffrey S. Sharp

Registration No.: 31,879
MARSHALL, GERSTEIN & BORUN LLP
233 S. Wacker Drive, Suite 6300
Sears Tower
Chicago, Illinois 60606-6357
(312) 474-6300
Attorney for Applicant

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

DECLARATION FOR PATENT APPLICATION

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name.

I believe I am an original, first and joint inventor of the subject matter which is claimed and for which a patent is sought on the invention entitled:

Drug Transport and Delivery System

the specification of which was filed on June 23, 2003 as International Application No. PCT/CH2003/000409.

I hereby state that I have reviewed and understand the contents of the above identified specification, including the claims, as amended by an amendment, if any, specifically referred to herein.

I acknowledge the duty to disclose all information known to me that is material to patentability in accordance with Title 37, Code of Federal Regulations, § 1.56.

FOREIGN PRIORITY CLAIM

I hereby claim foreign priority benefits under Title 35, United States Code § 119(a)-(d) of any foreign application(s) for patent or inventor's certificate listed below and have also identified below any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

☐ no such foreign applications have been filed

☒ such foreign application have been filed as follows:

EARLIEST FOREIGN APPLICATION(S), IF ANY FILED WITHIN 12 MONTHS
(6 MONTHS FOR DESIGN) PRIOR TO THIS U.S. APPLICATION

Application Number	Country	Date of Filing (dd/mm/yyyy)	Priority Claimed Under 35 USC 119
02017756.4	EP	June 24, 2002	<u> x </u> Yes No <u> </u>
02013916.8	EP	August 9, 2002	<u> x </u> Yes No <u> </u>
			<u> </u> Yes No <u> </u>

ALL FOREIGN APPLICATION(S), IF ANY FILED MORE THAN 12 MONTHS
(6 MONTHS FOR DESIGN) PRIOR TO THIS U.S. APPLICATION

Application Number	Country	Date of Filing (dd/mm/yyyy)

CLAIM FOR BENEFIT OF EARLIER U.S. PROVISIONAL APPLICATIONS

I hereby claim priority benefits under Title 35, United States Code §119(e), of any United States provisional patent application(s) listed below:

☒ no such U.S. provisional applications have been filed.

☐ such U.S. provisional application have been filed as follows:

Application Number	Date of Filing (dd/mm/yyyy)	Priority Claimed Under 35 USC 119
		<u> </u> Yes No <u> </u>
		<u> </u> Yes No <u> </u>
		<u> </u> Yes No <u> </u>

CLAIM FOR BENEFIT OF EARLIER U.S./PCT APPLICATION(S)

I hereby claim the benefit under Title 35, United States Code, §120 of the United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose all information that is material to patentability in accordance with Title 37, Code of Federal

Regulations, §1.56 which became available to me between the filing date of the prior application and the national or PCT international filing date of this application:

- ☐ no such U.S./PCT applications have been filed.
- ☒ such U.S./PCT application have been filed as follows:

Application Number	Date of Filing (dd/mm/yyyy)
PCT/CH2003/000409	June 23, 2003

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

I hereby appoint: _____

All practitioners at Customer Number 04743

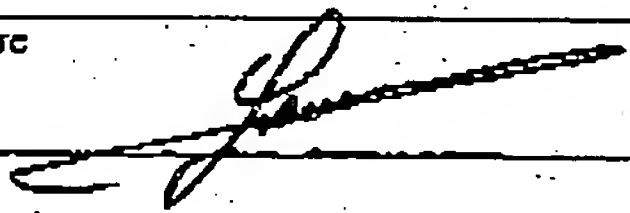
jointly, and each of them severally, my attorneys at law/patent agent(s), with full power of substitution, delegation and revocation, to prosecute this application, to make alterations and amendments therein, to receive the patent, and to transact all business in the U. S. Patent and Trademark Office connected therewith.

Please mail all correspondence to Jeffrey S. Sharp, whose address is:

MARSHALL, GERSTEIN & BORUN LLP
 233 S. Wacker Drive, Suite 6300
 Sears Tower
 Chicago, Illinois 60606-6357

Please direct telephone calls to: Jeffrey S. Sharp at (312) 474-6300.

Please direct facsimiles to: (312) 474-0448

Full name of sole or first inventor Ghanem E. Ghanem	
Sole or first inventor's signature 	Date 7 June 2006
Residence Brussels, Belgium	
Citizenship Belgium	
Mailing Address c/o Institut Jules Bordet Rue Héger-Bordet 1 B-1000 Brussels BELGIUM	

Full name of second inventor, if any Francesco Mehlem	
Second inventor's signature	Date
Residence Worblafen, Switzerland	
Citizenship Italy	
Mailing Address Lindenhofstrasse 2 CH-3048 Worblafen SWITZERLAND	

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Dated: Sep. 6, 2006

Signature:

Jeffrey S. Sharp

Docket No.: 27656/40760
(PATENT)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Patent Application of:
Ghanem et al.

Application No.: 10/518,610

Filed: Not Yet Assigned

For: DRUG TRANSPORT AND DELIVERY
SYSTEM

Confirmation No.: 3634

Art Unit: Not Yet Assigned

Examiner: Not Yet Assigned

DECLARATION OF GHANEM E. GHANEM.
PURSUANT TO 37 CFR § 1.48(a)

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Dear Sir:

I, Ghanem E. Ghanem, residing at c/o Institut Jules Bordet, Rue Heger-Bordet 1, B-1000, Brussels, Belgium, hereby declare that:

1. I am a co-inventor of the above-identified patent application along with Francesco Mehlem. I submit this declaration to make facts of record regarding Dr. Mehlem's initial cooperation regarding execution of a Declaration that was found to be defective by the United States Patent and Trademark Office and Dr. Mehlem's later refusal to cooperate and sign a corrected Declaration.

2. Specifically, I presented Dr. Mehlem with the Application papers including specification and claims (there were no drawings) and a Declaration (Declaration 1) between late March and early May 2005. Dr. Mehlem signed the Declaration and returned it to patent counsel so that it could be filed in the United States Patent and Trademark Office. I am informed that Declaration 1 was submitted to the USPTO in June 2005 but that in March 2006 the Declaration was found to be defective because it identified the application by its US application serial number and mailing date rather than its International application number and international filing date.

3. I was then supplied with a revised Declaration (Declaration 2) substituting the International application number and international filing date for the US Serial Number and Express mailing date. I signed a first copy of Declaration 2 and returned it to my patent counsel and then forwarded a second copy of Declaration 2 to Dr. Mehlem on June 14, 2006 with a request that he sign the declaration. A copy of the proofs of registration of the guaranteed mail to Dr. Mehlem is attached hereto as Exhibit A. Roughly two weeks later I received a letter from Dr. Mehlem dated June 28, 2006 in which Dr. Mehlem acknowledged receipt of my request that he execute Declaration 2. The letter, which is attached hereto as Exhibit B, states that because of differences between Dr. Mehlem and myself and for various other reasons including "the inability to bring the Delivery System to market" that he would not cooperate with me or provide his "consent for matters regarding the US Patent."

4. Because my June 14 letter requesting that Dr. Mehlem execute Declaration 2 was the only correspondence I had sent to Dr. Mehlem in a number of months I interpret Dr. Mehlem's refusal to provide "consent for matters regarding the US Patent" as a refusal to sign that Declaration. I further conclude that Dr. Mehlem will not execute the Declaration at this or any future time.

5. I further declare that all statements made herein of my own knowledge are true, that all statements made on information and belief are believed to be true, and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under 18 U.S.C. § 1001 and that such willful false statements may jeopardize the validity of the application or document or any patent which may issue thereon.

Date:

4 Sep 2006


Ghanem E. Ghanem

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EXHIBIT A

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LA POSTE - S.A. DE DROIT PUBLIC - CENTRE MONNAIE - 1000 BRUXELLES - RCB 566.374 - BE 214.596.464

201 PoD Int.

RECEPISSE DE DEPOT D'UN ENVOI RECOMMANDE

UNIQUEMENT DESTINE AUX ENVOIS INTERNATIONAUX

DESTINATAIRE

DR ROFF WEISS
E. BLUM & CO.
VORDERBERG 11
CH - 8044 ZÜRICH

EXPEDITEUR

G. GHANEM LOCE
INSTITUT J. BORDET
1 RUE MEGER BORDET
1000 BXL BELGIQUE

FRAIS :

6,20

EUR

☒ AR

R

R RR 157 80505 1 BE

AVIS

Conformément à nos conditions générales de vente art. VIII §3, les plaintes relatives aux envois internationaux peuvent être introduites dans un délai de 6 mois à compter du lendemain de la date de dépôt de l'envoi.



LA POSTE - S.A. DE DROIT PUBLIC - CENTRE MONNAIE - 1000 BRUXELLES - RCB 566.374 - BE 214.596.464

201 PoD Int.

RECEPISSE DE DEPOT D'UN ENVOI RECOMMANDE

UNIQUEMENT DESTINE AUX ENVOIS INTERNATIONAUX

DESTINATAIRE

MR F MEHLER
LINDENHOF STRASSE 2
CH - 3048 WORBLAU FEN

EXPEDITEUR

G. GHANEM LOCE
INSTITUT J. BORDET
1 RUE MEGER BORDET
1000 BXL BELGIQUE

FRAIS :

6,20

EUR

☒ AR

R

R RR 157 80504 8 BE

AVIS

Conformément à nos conditions générales de vente art. VIII §3, les plaintes relatives aux envois internationaux peuvent être introduites dans un délai de 6 mois à compter du lendemain de la date de dépôt de l'envoi.

01/01/08 - Bon D 8235 - Code ERP 2500000010309

EXHIBIT B

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Francesco Mehlem
Lindenhofstrasse 2
CH-3048 Worblaufen

Registered Letter

Prof. G.E. Ghanem
Université Libre de Bruxelles
Faculté de Médecine – Institut J. Bordet
LOCE
Rue Héger-Bordet 1 – CP 401
B-1000 Bruxelles

28 June 2006

Dear Prof. Ghanem

receipt is acknowledged of your request for my consent for matters regarding the US Patent. Given our many differences voiced over and again these past years; the inability to bring the Delivery System to market and all of the other reasons of which we are aware, I cannot in good conscience accede to your request.

Sincerely Yours,


Francesco Mehlem

CC: Mr. D. Porto, lawyer
Mr. Ch. Rapin, lawyer
Mr. R. Hagenbüchle, Administrator PTC Pharma AG
Mr. Simon, lawyer, Zurich
Patent lawyer office Blum, Zurich

Under the Paperwork Reduction Act of 1995, no person are required to respond to a collection of information unless it displays a valid OMB control number.

PETITION FEE Under 37 CFR 1.17(f), (g) & (h) TRANSMITTAL (Fees are subject to annual revision) Send completed form to: Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450	Application Number	10/518,610
	Filing Date	December 23, 2004
	First Named Inventor	Ghanem E. Ghanem
	Art Unit	Not Yet Assigned
	Examiner Name	Not Yet Assigned
	Attorney Docket Number	27656/40760

Enclosed is a petition filed under 37 CFR 1.47 that requires a processing fee (37 CFR 1.17(f), (g), or (h)). Payment of \$ 200.00 is enclosed.

This form should be included with the above-mentioned petition and faxed or mailed to the Office using the appropriate Mail Stop (e.g., Mail Stop Petition), if applicable. For transmittal of processing fees under 37 CFR 1.17(i), see form PTO/SB/17i.

Payment of Fees (small entity amounts are NOT available for the petition fees).

☒ The Commissioner is hereby authorized to charge the following fees to Deposit Account No. 13-2855 :
☐ petition fee under 37 CFR 1.17(f), (g) or (h) ☒ any deficiency of fees and credit of any overpayments

Enclose a duplicative copy of this form for fee processing.

☒ Check in the amount of \$ 200.00 is enclosed.

☐ Payment by credit card (Form PTO-2038 or equivalent enclosed). Do not provide credit card information on this form.

Petition Fees under 37 CFR 1.17(f): Fee \$400 Fee Code 1462

For petitions filed under:

- § 1.36(a) – for revocation of a power of attorney by fewer than all applicants.
- § 1.53(e) – to accord a filing date.
- § 1.57(a) – to accord a filing date.
- § 1.182 – for decision on a question not specifically provided for.
- § 1.183 – to suspend the rules.
- § 1.378(e) – for reconsideration of decision on petition refusing to accept delayed payment of maintenance fee in an expired patent.
- § 1.741(b) – to accord a filing date to an application under § 1.740 for extension of a patent term.

Petition Fees under 37 CFR 1.17(g): Fee \$200 Fee Code 1463


For petitions filed under:

- § 1.12 – for access to an assignment record.
- § 1.14 – for access to an application.
- § 1.47 – for filing by other than all the inventors or a person not the inventor.
- § 1.59 – for expungement of information.
- § 1.103(a) – to suspend action in an application.
- § 1.136(b) – for review of a request for extension of time when the provisions of section 1.136(a) are not available.
- § 1.295 – for review of refusal to publish a statutory invention registration.
- § 1.296 – to withdraw a request for publication of a statutory invention registration filed on or after the date the notice of intent to publish issued.
- § 1.377 – for review of decision refusing to accept and record payment of a maintenance fee filed prior to expiration of a patent.
- § 1.550(c) – for patent owner requests for extension of time in ex parte reexamination proceedings.
- § 1.956 – for patent owner requests for extension of time in inter partes reexamination proceedings.
- § 5.12 – for expedited handling of a foreign filing license.
- § 5.15 – for changing the scope of a license.
- § 5.25 – for retroactive license.

Petition Fees under 37 CFR 1.17(h): Fee \$130 Fee Code 1464

For petitions filed under:

- § 1.19(g) – to request documents in a form other than that provided in this part.
- § 1.84 – for accepting color drawings or photographs.
- § 1.91 – for entry of a model or exhibit.
- § 1.102(d) – to make an application special.
- § 1.138(c) – to expressly abandon an application to avoid publication.
- § 1.313 – to withdraw an application from issue.
- § 1.314 – to defer issuance of a patent.



Signature

Jeffrey S. Sharp

Typed or printed name

September 6, 2006
Date

31,879
Registration No., if applicable

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Dated: September 6, 2006

Signature:  (Jeffrey S. Sharp)